#### §417.7

#### §417.7 Training.

- (a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:
- (1) Development of the HACCP plan, in accordance with §417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and
- (2) Reassessment and modification of the HACCP plan, in accordance with §417.3 of this part.
- (b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

#### §417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

- (a) Reviewing the HACCP plan;
- (b) Reviewing the CCP records;
- (c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
  - (d) Reviewing the critical limits;
- (e) Reviewing other records pertaining to the HACCP plan or system;
- (f) Direct observation or measurement at a CCP;
- (g) Sample collection and analysis to determine the product meets all safety standards; and
- (h) On-site observations and record review.

# PART 424—PREPARATION AND PROCESSING OPERATIONS

#### Subpart A—General

Sec

424.1 Purpose and scope.

## Subpart C—Food Ingredients and Sources of Radiation

424.21 Use of food ingredients and sources of radiation.

424.22 Certain other permitted uses.

424.23 Prohibited uses.

AUTHORITY: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 451-470, 601-695; 7 CFR 2.18, 2.53.

Source: 64 FR 72175, Dec. 23, 1999, unless otherwise noted.

#### Subpart A—General

#### § 424.1 Purpose and scope.

This part of the regulations prescribes rules for the preparation of meat and the processing of poultry products. The rules in this part further the purposes of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) by, among other things, preventing the adulteration or misbranding of meat and poultry products at official establishments. 9 CFR Chapter III, Subchapter A, Parts 318 and 319, Subpart C of this part, and 21 CFR Chapter I, Subchapter A or Subchapter B, specify rules for the use of certain food ingredients (e.g., food additives and color additives) and sources of radiation that may render meat or poultry products adulterated or misbranded.

## Subpart C—Food Ingredients and Sources of Radiation

## § 424.21 Use of food ingredients and sources of radiation.

- (a)(1) *General.* No meat or poultry product shall bear or contain any food ingredient that would render it adulterated or misbranded, or which is not approved in this part, part 318 or part 319 of this chapter, or by the Administrator in specific cases.
- (2)(i) Poultry products and poultry broth used in the processing of poultry products shall have been processed in the United States only in an official establishment or imported from a foreign country listed in §381.196(b), and have been inspected and passed in accordance with the regulations. Detached ova and offal shall not be used in the processing of any poultry products, except that poultry feet may be processed

for use as human food in a manner approved by the Administrator in specific cases and detached ova may be used in the processing of poultry products if the processor demonstrates that such ova comply with the requirements of the Federal Food, Drug, and Cosmetic Act.

- (ii) Liquid, frozen, and dried egg products used in the processing of any poultry product shall have been prepared under inspection and be so marked in accordance with the Egg Products Inspection Act.
- (3)(i) Carcasses, parts thereof, and products of cattle, sheep, swine, goats, or equines may be used in the processing of poultry products only if they were prepared in the United States in an official meat packing establishment or imported from a foreign country listed in §327.2(b), were inspected and passed in accordance with the Federal Meat Inspection Act and the regulations under such Act (subchapter A of this chapter), and are so marked.
- (ii) Pork from carcasses or carcass parts used as an ingredient in poultry products that has been found free of trichinae, as described under §318.10 (a)(2), (e) and (f) of the Federal meatinspection regulations (9 CFR 318.10 (a)(2), (e) and (f)), is not required to be treated for the destruction of trichinae.
- (iii) Poultry products containing pork muscle tissue which the Administrator determines at the time the labeling for the product is submitted for approval in accordance with part 381 of the regulations in subchapter A or upon subsequent reevaluation of the product would be prepared in such a manner that the product might be eaten rare or without thorough cooking because of the appearance of the finished product or otherwise, shall be effectively heated, refrigerated, or cured to destroy any possible live trichinae, as prescribed in §318.10(c) of this chapter, at the official establishment where such products are prepared. In lieu of such treatment of poultry products containing pork, the pork ingredient may be so treated.
- (b)(1) Food ingredients and sources of radiation. Food ingredients and sources of radiation listed or approved for use in the production of meat or poultry

- products in 21 CFR chapter I, subchapter A or subchapter B, shall be listed for such use under this chapter, subject to declaration requirements in parts 316 and 317, or subparts M and N, of part 381 of this chapter, unless precluded from such use or further restricted in parts 318 or 319, or subparts O and P, of part 381 of this chapter, or unless such use otherwise results in the adulteration or misbranding of meat or poultry products. Food ingredients and sources of radiation listed or approved for use in the production of meat or poultry products in 21 CFR Chapter I, subchapter A or subchapter B, may be listed or approved for such use under this chapter by the Administrator in §424.21, subject to declaration requirements in parts 316 and 317, or subparts M and N, of part 381 of this chapter.
- (2) No food ingredients or sources of radiation may be used in the preparation of any meat or poultry product, for any purpose, unless the use is listed or approved in 21 CFR chapter I as a direct food additive (21 CFR part 172), a secondary direct food additive (21 CFR part 173), indirect food additive (21 CFR parts 174–178), radiation source (21 CFR part 179), an interim-listed direct food additive (21 CFR part 180), a prior-sanctioned substance (21 CFR part 181), a Generally Recognized As Safe (GRAS) substance (21 CFR parts 182 or 184), or by a regulation in this chapter. Part 319 of this chapter also specifies other food ingredients that are acceptable in preparing specified products.
- (3) No food ingredient, the intended use of which is to impart color in any meat or poultry product, shall be used unless such use is approved in 21 CFR Chapter I as a color additive (21 CFR Parts 73, 74, 81, and 82) or in a regulation in this chapter.
- (4) Petitions to amend 21 CFR chapter I to provide for uses of food additives, or other substances or sources of radiation necessary in the preparation of meat or poultry products, or food ingredients used to impart color to product, should be sent to the Food and Drug Administration, in accordance with the provisions of 21 CFR parts 71 or 171, as appropriate.
- (5) Inquiries concerning the regulatory status under the Federal Food, Drug, and Cosmetic Act of any articles

#### § 424.21

intended for use as components of, or in contact with, meat or poultry products, may be addressed to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204, or the Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program Development and Evaluation, Washington, DC 20250-3700.

(6) Inquiries concerning the use in specific meat or poultry products of substances that are not affirmed by the Food and Drug Administration as Generally Recognized as Safe (GRAS) or otherwise listed in 21 CFR Part 182 or Part 184, or of food or color additives listed in 21 CFR regulations for general use in foods or for use in meat, or poultry products, generally, including mixtures of such substances or additives, should be addressed to the Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program

Development and Evaluation, Washington, DC 20250-3700.

(c) The food ingredients specified in the following chart are approved for use in the preparation of meat products, provided they are used for the purposes indicated, within the limit of the amounts stated, and under other conditions specified in this part and Part 317 of this chapter. Part 319 of this chapter specifies other food ingredients that are acceptable in preparing specified meat products. This chart also contains food ingredients that are acceptable for use in poultry products, provided they are used for the purpose indicated, within the limits of the amounts stated and under other conditions specified in this part. No meat or poultry product shall bear or contain any food ingredient that would render it adulterated or misbranded, or which is not approved in this part, or by the Administrator in specific cases.

Class of substance	Substance	Purpose	Products	Amount
Acidifiers	Acetic acid	To adjust acidity	Various meat and poultry products <sup>2</sup> .	Sufficient for purpose.3
	Citric acid	do	do	Do.
	Glucono delta-lac- tone.	do	do	Do.
	Lactic acid	do	do	Do.
	Phosphoric acid	do	do	Do.
	Tartaric acid	do	do	Do.
Anti-coagulants	Citric acid	To prevent clotting	Fresh blood of livestock	0.2 percent with or without water. When water is used to make a solution of citric acid added to the blood of livestock, not more than 2 parts of water to 1 part of citric acid shall be used.  Not to exceed 0.5 percent based on the ingoing weight of the product. When water is used to make a solution of sodium citrate added to livestock blood, not more than 2 parts of water to 1 part of sodium citrate
Antifooming agent	Methyl polysilicone	To retard foaming	Soups (meat and poultry)	shall be used. 10 ppm.
Antifoaming agent	weary polysilicone	do	Rendered fats (meat and poultry)	Do.
		do	Curing pickle (meat and poultry).	50 ppm.
Antimicrobial Agents	Potassium lactate	To inhibit microbial growth.	Various meat and poultry products, except infant formulas and infant food.	4.8% by weight of total formulation.
	Sodium diacetate	do	do	0.25% by weight of total formulation.
	Sodium lactate	do	do	4.8% by weight of total formulation.

## § 424.21

Class of substance	Substance	Purpose	Products	Amount
	Trisodium phos- phate.	To reduce microbial levels.	Raw, chilled poultry car- casses.	8 to 12 percent; solution to be maintained at 45 °F. to 55 °F. and applied by spraying or dipping car- casses for up to 15 sec- onds when used in ac- cordance with 21 CFR 182.1778.
Antioxidants and oxygen interceptors.	Ascorbyl palmitate  Ascorbyl stearate.	To retard rancidity	Margarine or oleomargarine	0.02 percent (by wt. of fin- ished product) individually or in combination with other antioxidants ap- proved for use in mar- garine.
	BHA (butylated hy-			
	droxyanisole). do	Dry sausage	0.003 based on total weight	0.006 percent in combina-
		Dry sausage	0.000 based on total weight	tion with other anti- oxidants for use in meat.
	do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination with other anti-oxidants for use in meat.
	do	Fresh pork, sau- sage, brown and serve sausages, fresh Italian sau- sage products, pregrilled beef patties, fresh sau- sage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination with other anti-oxidants for use in meat, based on fat content.
	do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination with other anti-oxidants for use in meat.
	do	Margarine or oleo- margarine.	0.02 percent (by wt. of the finished product) individ- ually or in combination with other antioxidants approved for use in mar- garine	
	do	Various poultry products.	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry) based on fat content	
	BHT (butylated hydroxytoluene).	do	Dry sausage	0.003 percent based on total weight 0.006 percent in combination with other anti-oxidants for use in meat.
	do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination with other anti-oxidants for use in meat.

## 9 CFR Ch. III (1-1-06 Edition)

Class of substance	Substance	Purpose	Products	Amount
	do	Fresh pork, sau- sage, brown and serve sausages, fresh Italian sau- sage products, pregrilled beef patties, fresh sau- sage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination with other anti-oxidants for use in meat, based on fat content.
	do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination with other anti-oxidants for use in meat.
	do	Margarine or oleo- margarine.	0.02 percent (by wt. of the finished product) individ- ually or in combination with other antioxidants approved for use in mar- garine	
	do	Various poultry products.	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry) based on fat content	
	Dodecyl gallate	do	Margarine or oleomargarine	0.02 percent (by wt. of the finished product) individ- ually or in combination with other antioxidants approved for use in mar- garine.
	Glycine	do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent 0.02 percent in combination with other anti-oxidants for use in meat.
	Octyl gallate	do	Margarine or oleomargarine	0.02 percent (by wt. of the finished product) individ- ually or in combination with other antioxidants approved for use in mar- garine.
	Propyl gallate	do	Dry sausage	0.003 percent based on total weight 0.006 percent in combination with other anti-oxidants for use in meat.
	do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination with other anti-oxidants for use in meat.
	do	Fresh pork, sau- sage, brown and serve sausages, fresh Italian sau- sage products, pregrilled beef patties, fresh sau- sage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination with other anti-oxidants for use in meat, based on fat content.
	do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination with other anti-oxidants for use in meat.

Class of substance	Substance	Purpose	Products	Amount
	do	Margarine or oleo- margarine.	0.02 percent (by wt. of the finished product) individ- ually or in combination with other antioxidants approved for use in mar- garine	
	do	Various poultry products.	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry, except TBHQ, based on fat content)	
	Resin guaiac	do	Rendered animal fat or a combination of such fat and vegetable fat 0.01 percent.	0.02 percent in combination with other antioxidants for use in meat.
	TBHQ (tertiary butylhydroquinon-e).	do	Dry sausage 0.003 percent based on weight.	0.006 percent in combination only with BHA and/or BHT.
	do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combina- tion only with BHA or BHT.
	do	Fresh pork, sau- sage, brown and serve sausages, fresh Italian sau- sage products, pregrilled beef pattles, fresh sau- sage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination only with BHA and/ or BHT, based on fat content.
	do	Dried meatsdo	0.01 percent based on total weight.  Margarine or oleo-mar-	0.01 percent in combina- tion only with BHA and/or BHT. 0.02 percent alone or in
			garine.	combination only with BHA and/or BHT, based on oil or fat content.
		do	Various poultry products	0.01 percent based on fat content (0.02 percent in combination only with BHA and/or BHT, based on fat content).
	Tocopherols	do	Rendered animal fat or a combination of such fat and vegetable fat.	0.03 percent. A 30 percent concentration of tocopherols in vegetable oils shall be used when added as an antioxidant to products designated as "lard" or "rendered pork fat."
		do	Dry sausage, semidry sau- sage, dried meats, uncooked or cooked fresh sausage made with beef and/or pork, uncooked or cooked Italian sausage products, uncooked or cooked meatballs, uncooked or cooked meat pizza toppings, brown and serve sausages, pregrilled beef patties, and restructured meats.	Not to exceed 0.03 percent based on fat content. Not used in combination with other antioxidants.

## 9 CFR Ch. III (1-1-06 Edition)

Class of substance	Substance	Purpose	Products	Amount
		do	Various poultry products	0.03 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry, except TBHQ, based on fat content).
Artificial Sweeteners Binders and Extend- ers.	SaccharinAgar-agar	To sweeten product To stabilize and thicken.	Bacon Thermally processed canned and jellied meat food products.	0.01 percent. 0.25 percent of finished product.
	Algin	To extend and sta- bilize product.	Breading mix; sauces (meat only) and various poultry products.	Sufficient for purpose in ac cordance with 21 CFR 172.5.
	A mixture of sodium alginate, calcium carbonate and calcium lactate/ lactic acid (or glucono delta lac- tone).	To bind meat pieces	Restructured meat food products.	Sodium alginate not to exceed 1.0 percent; calcium carbonate not to exceed 0.2 percent; and lactic acid/calcium lactate (or glucono delta-lactone) not to exceed 0.3 percent of product formulation.  Added mixture may not exceed 1.5 percent of product at formulation.  Mixture ingredients must be added dry.
	A mixture of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.	To bind poultry pieces.	Ground and formed raw or cooked poultry pieces.	Sodium alginate not more than 0.8 percent, calcium carbonate not more than 0.15 percent; lactic acid and calcium lactate, in combination, not more than 0.6 percent of product formulation. Added mixture may not exceed 1.55 percent of product a formulation. The mixture must be added in dry form.
	Bread	To bind and extend product.	Bockwurst	3.5 percent individually or collectively with other binders for use in meat.
		do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat.
		do	Spaghetti with meat balls and sauce, spaghetti with meat and sauce and simi- lar products.	12 percent individually or collectively with other binders for use in meat.
	Carboxymethyl cel- lulose (cellulose gum).	To extend and sta- bilize product.	Baked pies (meat only) and various poultry products.	Sufficient for purpose in ac cordance with 21 CFR 172.5.
(	Carrageenan	To extend and sta- bilize product.	Breading mix; sauces (meat only) and various poultry products.	Sufficient for purpose in ac cordance with 21 CFR 172.5.
		To prevent purging of brine solution.	Cured pork products as provided in 9 CFR 319.104(d).	Not to exceed 1.5 percent of product formulation; permitted in combination only with soy protein con centrate, combination not to exceed 1.5 percent of product formulation; in ac cordance with 21 CFR 172.620, 172.623, and 172.626.

Class of substance	Substance	Purpose	Products	Amount
	Carrageenan, Lo- cust bean gum, and Xanthan gum blend.	do	do	In combination, not to exceed 0.5 percent of formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.620, 172.623, 172.626, 184.1343, and 172.695.
	Cereal	To bind and extend product.	Sausages as provided in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders for use in meat.
		do	Chili con carne, chili con carne with beans.	8 percent individually or col- lectively with other bind- ers for use in meat.
	Dried milk	do	Sausages as provided for in 9 CFR Part 319.	3.5 percent individually or collectively with other binders for use in meat
	Dried skim milk, cal- cium reduced.	do	Sausages as provided in 9 CFR 9 CFR Part 319.	Do.
		do	Chili con carne, chili con carne with beans.	8 percent individually or col- lectively with other bind- ers for use in meat.
	Enzyme (rennet) treated with calcium reduced dried skim milk and calcium lactate.	do	Sausages as provided for in 9 CFR Part 319.	3.5 percent total finished product (calcium lactate required at rate of 10 per- cent of binder.)
		do	Imitation sausages; nonspe- cific loaves; soups, stews (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5 (calcium lactate required at a rate of 10 percent of binder).
	Enzyme (rennet) treated with so- dium caseinate and calcium lac- tate.	do	Imitation sausages; nonspe- cific loaves; soups, stews (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5 (calcium lactate required at a rate of 25 percent of binder).
	Food starch modified.	To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 2 percent of product formulation in "Ham Water Added" and "Ham with Natural Juices" products; not to exceed 3.5 percent of product formulation in "Ham and Water Product—X percent of Weight is Added Ingredients" products; permitted in combination only with soy protein concentrate, with combination of modified food starch at 3 percent of product formulation and soy protein concentrate at 0.5 percent of product formulation; in ac cordance with 21 CFR 172.892.
	Gelatin	To bind and extend product.	Various poultry products	Sufficient for purpose in accordance with 21 CFR 172.5.
	Gums, vegetable	do	Egg roll (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
	Isolated soy protein	do	Sausage as provided for in 9 CFR Part 319, bockwurst.	2 percent.

Class of substance	Substance	Purpose	Products	Amount
		do	Imitation sausages; nonspe- cific loaves; soups; stews (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
		do	Chili con carne, chili con carne with beans.	8 percent individually or col- lectively with other bind- ers for use in meat.
		do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and simi- lar products.	12 percent individually or collectively with other binders and extenders for use in meat.
		To prevent purging of brine solution.	Cured pork products as pro- vided for in 9 CFR 319.104(d).	Not to exceed 2 percent of product formulation, not permitted in combination with other binders approved for use in cured pork products.
	Methyl cellulose	To extend and sta- bilize product (also carrier).	Meat and vegetable patties; various poultry products.	0.15 percent.
	Sodium caseinate	To bind and extend product.	Imitation sausages, nonspe- cific loaves, soups, stews (meat only).	Sufficient for purpose in accordance with 21 CFR 182.1748 and 21 CFR 172.5.
		do	Sausages as provided for in 9 CFR Part 319.	2 percent in accordance with 21 CFR 182.1748.
		do	Chili con carne, chili con carne with beans.	percent individually or collectively with other binders and extenders for use in meat in accordance with 21 CFR 182.1748.
		do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and simi- lar products.	12 percent individually or collectively with other binders and extenders for use in meat in accord- ance with 21 CFR 182.1748.
		To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products, in accordance with 21 CFR 182.1748.
		To bind and extend product.	Various poultry products	3 percent in cooked prod- uct, 2 percent in raw product, in accordance with 21 CFR 172.5 and 182.1748.
	Soy flour	do	Sausages as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		do	Chili con carne, chili con carne with beans.	8 percent individually or col- lectively with other bind- ers and extenders for use in meat.
		do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and simi-	12 percent individually or collectively with other binders and extenders for
	Soy protein concentrate.	do	lar products. Sausage as provided for in 9 CFR Part 319, bockwurst.	use in meat. 3.5 percent individually or collectively with other binders for
		do	Chili con carne, chili con carne with beans.	use in meat. 8 percent individually or collectively with other binders and extenders for use in meat.
		do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and simi- lar products.	12 percent individually or collectively with other binders and extenders for use in meat.

Class of substance	Substance	Purpose	Products	Amount
		To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 3.5 percent of product formulation; permitted in combination only with modified food starch, with combination of modified food starch a 3 percent of product formulation and soy protein concentrate at 0.5 percent of product formulation; in combination only with carrageenan, combination not to exceed 1. percent of product formulation;
	Starchy vegetable flour.	To bind and extend product.	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders fo use in meat.
		do	Chili con carne, chili con carne with beans.	percent individually or collectively with other binders and extenders for use in meat.
	Tapioca dextrin	do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders fo use in meat, in accordance with 21 CFR 184.1277.
		do	Chili con carne, chili con carne with beans.	8 percent individually or co lectively with other bind- ers and extenders for us- in meat, in accordance with 21 CFR 184.1277.
		do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and simi- lar products.	12 individually or collectivel with other binders and ex- tenders for use in meat, in accordance with 21 CFR 184.1277.
		do	Various poultry products	Sufficient for purpose in ac cordance with 21 CFR 184.1277.
	Vegetable starch	do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders fo use in meat.
		do	Chili con carne, chili con carne with beans.	percent individually or co lectively with other bind- ers and extenders for us in meat.
	Wheat gluten	To bind and extend product.	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders fo use in meat, in accord- ance with 21 CFR 184.1322.
		do	Chili con carne, chili con carne with beans.	8 percent individually or co lectively with other bind- ers for use in meat, in ac cordance with 21 CFR 184.1322.
		do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and simi- lar products.	12 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1322.
		do	Various poultry products	Sufficient for purpose in accordance with 21 CFR 184.1322.

		T	T	T
Class of substance	Substance	Purpose	Products	Amount
	Whey, Dry or dried	To bind or thicken	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		do	Imitation sausages, nonspe- cific loaves, soups, stews (meat only).	8 percent individually or col- lectively with other bind- ers and extenders for use in meat.
		do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or col- lectively with other bind- ers and extenders for use in meat.
		do	Various poultry products	Sufficient for purpose in accordance with 21 CFR 184.1322.
	Whey, Reduced lactose.	To bind or thicken	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		do	Imitation sausages, nonspe- cific loaves, soups, stews (meat only).	Sufficient for purpose in accordance with 21 CFR 172.5.
		do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or col- lectively with other bind- ers and extenders for use in meat.
	Whey, Reduced minerals.	do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		do	Imitation sausages, nonspe- cific loaves, soups, stews (meat only).	Sufficient for purpose in accordance with 21 CFR 172.5.
		do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or col- lectively with other bind- ers and extenders for use in meat.
	Whey protein concentrate.	do	Sausage as provided in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1979c.
		do	Imitation sausages, nonspecific loaves, soups, stews.	Sufficient for purpose in accordance with 21 CFR 184.1979c.
		do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or col- lectively with other bind- ers and extenders for use in meat, in accordance with 21 CFR 184.1979c
		To bind meat pieces	Restructured meat food products, whole muscle meat cuts.	3.5 percent individually or collectively with other binders and extenders for use in meat, in accord- ance with 21 CFR 184.1979c.
	Xanthan gum	To maintain: uniform viscosity; suspension of particulate matter, emulsion stability; freezethaw stability.	Meat sauces, gravies or sauces and meats, canned or frozen and/or refrigerated meat salads, canned or frozen meat stews, canned chili or chili with beans, pizza topping mixes and batter or breading mixes.	Sufficient for purpose in accordance with 21 CFR 172.5.
		do	Various poultry products, except uncooked prod- ucts or sausages or other products with a moisture limitation established by Subpart P of Part 381.	Sufficient for purpose

Class of substance	Substance	Purpose	Products	Amount
Bleaching Agent	Hydrogen peroxide	To remove color	Tripe (substance must be removed from product by rinsing with clear water).	Sufficient for purpose.
Catalysts (sub- stances must be eliminated during process).	Nickel	To accelerate chemical reaction.	Rendered animal fats or a combination of such fats and vegetable fats.	Do.
	Sodium amide	Rearrangement of fatty acid radicals.	do	Do.
Chilling Media	Sodium methoxide Salt (NaCl)	do To aid in chilling	Raw poultry products	700 lbs. to 10,000 gallons of water.
Coloring Agents (artificial).	Coal tar dyes (FD&C certified).	To color products	Various poultry products	Sufficient for purpose.
	Color additives list- ed in 21 CFR Part 74, Subpart A of Part 82, Subpart B (operator must furnish evidence to inspector in charge that color additive has been certified for use in connection with foods by the Food and Drug Admin- istration).	To color casings or rendered fats; marking and branding product.	Sausage casings, oleo- margarine, shortening, marking or branding ink on product (meat only).	Sufficient for purpose (may be mixed with approved natural coloring matters or harmless inert material such as common salt and sugar).
	Titanium oxide	To whiten	Canned ham salad spread and creamed-type canned meat products. Poultry salads and poultry spreads.	0.5 percent.
Coloring Agents (nat- ural).	Alkanet, annatto, carotene, cochi- neal, green chlo- rophyll, saffron and tumeric.	To color casings or rendered fats; marking and branding product.	Sausage casings, oleo- margarine, shortening, marking or branding ink on product (meat only).	Sufficient for purpose (may be mixed with approved artificial dyes or harmless inert material such as common salt and sugar).
Curing accelerators (must be used only in combination with curing agents).	Annatto, carotene Ascorbic acid	To color products To accelerate color fixing or preserve color during storage.	Various poultry products Cured pork and beef cuts, cured poultry, cured comminuted poultry and meat food products.	Sufficient for purpose. 75 oz to 100 gal pickle at 10 percent pump level; %4 oz to 100 lb meat, meat byproduct or poultry prod- uct; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product).
	Citric acid or sodium citrate.	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product, cured comminuted comminuted poultry or poultry products.	May be used in cured meat products or in 10 percent solution used to spray surfaces of cured meat cuts prior to packaging to replace up to 50 percent of the ascorbic acid, erythorbic acid, sodium ascorbate, or sodium erythorbate that is used. May be used in cured poultry products to replace 50 percent of the ascorbic acid or sodium ascorbate that is used.

## 9 CFR Ch. III (1-1-06 Edition)

Class of substance	Substance	Purpose	Products	Amount
	Erythorbic acid	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured poultry, cured comminuted poultry and meat food products.	75 oz to 100 gal pickle at 10 percent pump level; 3/ 4 oz to 100 lb meat, meat byproduct or poultry prod- uct; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product).
	Fumaric acid	do	Cured, comminuted meat, poultry or meat and poul- try products.	0.065 percent (or 1 oz to 100 lb) of the weight of the meat, poultry or the meat or poultry byprod- ucts before processing.
	Glucono delta lactone.	do	Cured, comminuted meat or meat food product. Genoa salami	8 oz to each 100 lb of meat or meat byproduct. 16 oz to 100 lb of meat (1.0
	Sodium acid pyrophosphate.	do	Frankfurters, wieners, vienna, bologna, garlic bologna, knockwurst and similar products.	percent). Not to exceed alone or in combination with other curing accelerators for use in meat the following: 8 oz in 100 lb of meat, or meat and meat byproducts, content of the formula; nor 0.5 percent in the finished product.
	Sodium ascorbate	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product, cured comminuted poultry or poultry products.	87.5 oz to 100 gal pickle at 10 percent pump level; % oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product).
	Sodium erythorbate	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food products, cured comminuted poultry or poultry products.	87.5 oz to 100 gal pickle at 10 percent pump level; % oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
Curing Agents	Sodium or potas- sium nitrate.	Source of nitrite	Cured meat products other than bacon. Nitrates may not be used in baby, jun- ior, and toddler foods. Cured, comminuted poul- try or poultry products.	7 lb to 100 gal pickle; 3½ oz to 100 lb meat or poultry product (dry cure); 2¾ oz to 100 lb chopped meat or poultry.

Class of substance	Substance	Purpose	Products	Amount
	Sodium or potas- sium nitrite (sup- plies of sodium ni- trite and potas- sium nitrite and mixtures con- taining them must be kept under the care of a respon- sible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accord- ingly).	To fix color	Cured meat and poultry products. Nitrites may not be used in baby, junior, or toddler foods.	2 lb to 100 gal pickle at 10 percent pump level; 1 oz to 100 lb meat or poultry product (dry cure); 1/4 oz to 100 lb chopped meat, meat byproduct or poultry product. The use of nitrites, nitrates or combination shall not result in more than 200 ppm of nitrite, calculated as sodium nitrite in finished product, except that nitrites may be used in bacon only in accordance with paragraph (b) of this section.
Denuding Agents (may be used in combination. Must be removed from tripe by rinsing with potable water.).	Lime (calcium oxide, calcium hydroxide).	To denude mucous membranes.	Tripe	Sufficient for purpose.
	Sodium carbonate	do	do	Do.
	Sodium citrate	do	do	Do.
	Sodium gluconate	do	do	Do.
	Sodium hydroxide	do	do	Do.
	Sodium persulfate	do	do	Do.
	Sodium silicates (ortho, meta, and sesqui).	do	do	Do.
	Trisodium phos- phate.	do	do	Do.
Emulsifying Agents	Actylated monoglycerides.	To emulsify product	Shortening and various poultry products.	Sufficient for purpose.
	Diacetyl tartaric acid esters of mono- and diglycerides.	do	do	Do.
	Glycerol-lacto stea- rate, oleate, or palmitate.	do	do	Do.
	Lecithin	To emulsify product (also as an antioxidant).	Oleomargarine, shortening, various meat and poultry products.	0.5 percent in oleo- margarine, use in other products—sufficient amount for emulsification.
	Mono and diglycerides (glycerol palmitate, etc.).	To emulsify product	Rendered animal fat or a combination of such fat with vegetable fat; oleomargarine.	Sufficient for purpose in lard and shortening; 0.5 percent in oleomargarine.
	,	do	Various poultry products	Sufficient for purpose.
	Mono and diglycerides of fatty acids esterified with any of the following acids: acetic, acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts; the sodium	do	Margarine or oleomargarine	0.5 percent.
	sulfoacetate de- rivatives of these mono and diglycerides.			

Class of substance	Substance	Purpose	Products	Amount
	Polyglycerol esters of fatty acids (polyglycerol esters of fatty acids are restricted to those up to and including the decaglycerol esters and otherwise meeting the requirements of § 172.854(a) of the Food Additive Regulations).	do	Rendered animal fat or a combination of such fat with vegetable fat when use is not precluded by standards of identity of composition; oleomargarine.	Sufficient for purpose for rendered animal fat or combination with vegetable fat; 0.5 percent for oleomargarine.
	Polysorbate 60 (polyoxyethylene (20) sorbitan monostearate).	do	Shortening for use in non- standardized baked goods, baking mixes, icings, fillings, and top- pings and in the frying of foods (meat only). Ren- dered poultry fat or a combination of such fat with vegetable fat.	1 percent when used alone. If used with polysorbate 80 the combined total shall not exceed 1 per- cent.
	Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate).	do	Shortening for use in non- standardized baked goods, baking mixes, icings, fillings, and top- pings and in the frying of foods (meat only). Var- ious poultry products.	percent when used alone. If used with polysorbate 60 the combined total shall not exceed 1 per- cent.
	1,2-propylene glycol esters of fatty acids.	do	Margarine or oleomargarine	2.0 percent.
	Propylene glycol mono and diesters of fats and fatty acids.	do	Rendered animal or poultry fat or a combination of such fat with vegetable fat.	Sufficient for purpose.
	Stearyl-2-lactylic acid.	do	Shortening to be used for cake icings and fillings (meat only).	3.0 percent.
	Stearyl monoglyceridyl citrate.	do	Shortening	Sufficient for purpose
Film Forming Agents	A mixture consisting of water, sodium alginate, calcium chloride, sodium carboxymethyl- cellulose, and corn syrup solids.	To reduce cooler shrinkage and help protect sur- face.	Freshly dressed meat car- casses. Such carcasses must bear a statement "Protected with a film of water, corn syrup solids, sodium alginate, calcium chloride and sodium carboxymethyl-cellulose.".	Formulation may not exceed 1.5 percent of hot carcass weight when applied. Chilled weight may not exceed hot weight.
Flavoring Agents; Protectors and Developers.	Artificial smoke flavoring.	To flavor product	Various (meat and poultry) <sup>2</sup>	Sufficient for purpose.
	Autolyzed yeast ex- tract.	do	do	Do.
	Benzoic acid (so- dium, potassium and calcium salts).	To retard flavor reversion.	Margarine or oleomargarine	0.1 percent individually, or if used in combination with other flavoring agents for use in meat or with sorbic acid and its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).
	Calcium lactate	To protect flavor	Cooked semi-dry and dry products including sausage, imitation sausage, and nonspecific meat food sticks.	0.6 percent in product formulation.
	Citric acid	do	Various poultry products Chili con carne	Sufficient for purpose. Do.

Comp our in colidar	I .		
Corn syrup solids; corn syrup; glu- cose syrup.	To flavor product	Various poultry products, sausage, hamburger, meat loaf, luncheon meat, chopped or pressed ham.	Do.
Dextrose	do	Sausage, ham and cured products.	Do.
Disodium guanylate	do	Oleomargarine Various meat and poultry products. <sup>2</sup>	Do.
Disodium inosinate Harmless bacteria starters of the aci- dophilus type, lac- tic acid starter or culture of Pediococcus cerevisiae.	To develop flavor	do Dry sausage, pork roll, thuringer, lebanon bolo- gna, cervelat, and salami.	Do. 0.5 percent.
Harmless lactic acid producing bacteria.	To prevent the growth of Clos-tridium botulinum.	Bacon	Sufficient for purpose.
Hydrolyzed plant protein.	To flavor product	Various meat and poultry products. <sup>2</sup>	Do.
Isopropyl citrate Malt syrup	To protect flavor To flavor product	Oleomargarine Cured meat products Various poultry products	0.02 percent. 2.5 percent. Sufficient for purpose.
Milk protein hydroly- sate.	do	Various meat and poultry products. <sup>2</sup>	Do.
Monoammonium glutamate.	do	do	Do.
Monosodium glu- tamate.	do	do	Do.
Potassium lactate	do	Various meat and meat food products, poultry and poultry food products, ex- cept infant formula and infant food. <sup>2</sup>	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1639.
Smoke flavoring	To flavor product	Various meat and poultry products.	Sufficient for purpose.
Sodium acetate	To flavor products	Various meat and poultry products.	Not to exceed 0.25% of for- mulate in accordance with 21 CFR 184.1721.
Sodium diacetate	do	do	Not to exceed 0.25% of for- mulate in accordance with 21 CFR 184.1754.
Sodium lactate	do	Various meat and meat food products, poultry and poultry food products, ex- cept infant formula and infant food. <sup>2</sup>	Not to exceed 2 percent of formulation in accordance with 21 CFR 184.1768.
Sodium sulfoacetate derivative of mono and diglycerids.	do	Various meat and poultry products. <sup>2</sup>	0.5 percent.
Sodium tripolyphosphate.	To help protect flavor.	"Fresh Beef," <sup>2</sup> "Beef for further cooking, "Cooked Beef," Beef Patties, Meat Loaves, Meat Toppings, and similar products derived from pork, lamb, veal, mutton, and goat meat which are cooked or frozen after processing.	0.5 percent of total product.
Sodium tripolyphosphate and sodium mix- tures, metaphosphate, insoluble; and so- dium polyphosphates,	do	do	Do.

## 9 CFR Ch. III (1-1-06 Edition)

Class of substance	Substance	Purpose	Products	Amount
	Sorbitol	To flavor, to facilitate the removal of casings from product, and to reduce caramelization and charring.	Cooked sausage labeled frankfurter, frank, furter, wiener, and knockwurst; cured pork and pork prod- ucts, as provided for in 9 CFR Part 319.	Not to exceed 2 percent of the weight of the formula excluding the formula weight of water or ice, when used in accordance with 21 CFR 184.1835.
	Starter distillate	To help protect flavor.	Oleomargarine	Sufficient for purpose.
	Stearyl citrate Sugars (sucrose	do To flavor product	Various meat and poultry	0.15 percent. Sufficient for purpose.
Gases	and dextrose). Carbon dioxide liq-	Contact freezing	products. Various poultry products	Do.
	uid. Carbon dioxide solid (dry ice).	To cool product	Chopping of meat, packing of product.	Sufficient for purpose.
	(ury ice).	To cool product or facilitate chopping or packaging.	Various poultry products	Do.
	Nitrogen	To exclude oxygen from sealed containers.	Various meat and poultry products.	Do.
	Nitrogen, liquid	Contact freezant	do	Do.
Hog Scald Agents (must be removed by subsequent cleaning oper- ations).	Caustic soda	To remove hair	Hog carcasses	Sufficient for purpose.
····	Dicotyl sodium sulfosuccinate.	do	do	Do.
	Dimethylpolysiloxan- e.	do	do	Do.
	Disodium-calcium ethylenediaminet- etra-acetate.	do	do	Do.
	Disodium phosphate	do	do	Do.
	Ethylenediaminetetr- a-acetic acid (so- dium salts).	do	do	Do.
	Lime (calcium oxide, calcium hydrox-ide).	do	do	Do.
	Potassium hydrox- ide.			Do.
	Propylene glycol Soap (prepared by the reaction of calcium, potas- sium, or sodium with rosin or fatty	do	do	Do. Do.
	acids of natural fats and oils). Sodium acid	da	da	Do.
	pyrophosphate.	do	do	
	Sodium carbonate Sodium	do	do	Do.
	dodecylbenzene sulfonate.	do	do	D0.
	Sodium gluconate	do	do	Do.
	Sodium hexametaphosphate.	do	do	Do.
	Sodium lauryl sul- fate.	do	do	Do.
	Sodium mono and dimethylnaphthalene sulfonate (molecular weight 245–260).	do	do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Sodium n-	do	do	Do.
	alkylbenzene			
	sulfonate (alkyl group predomi-			
	nantly C12 and			
	C13 and not less			
	than 95 percent C10 and C16).			
	Sodium	do	do	Do.
	pyrophosphate.			
	Sodium silicates	do	do	Do.
	(ortho, meta, and sesqui).			
	Sodium sulfate	do	do	Do.
	Sodium	do	do	Do.
	tripolyphosphate. Sucrose	do	do	Do.
	Triethanolamine	do	do	Do.
	dodecylbenzene			
	sulfonate.			
	Trisodium phos- phate.	do	do	Do.
Miscellaneous	Adipic acid	To acidify	Margarine or oleomargarine	Sufficient for purpose.
	Ascorbic acid,	To delay discolora-	Fresh beef cuts, fresh lamb	Not to exceed, singly or in
	erythorbic acid,	tion.	cuts, and fresh pork cuts.	combination, 500 ppm or
	citric acid, sodium ascorbate and so-			1.8 mg/sq inch of product surface of ascorbic acid
	dium citrate, sin-			(in accordance with 21
	gly or in combina-			CFR 182.3013),
	tion.			erythorbic acid (in accord- ance with 21 CFR
				182.3041), or sodium
				ascorbate (in accordance
				with 21 CFR 182.3731);
				and/or not to exceed, sin- gly or in combination, 250
				ppm or 0.9 mg/sq inch of
				product surface of citric
				acid (in accordance with
				21 CFR 182.6033), or so- dium citrate (in accord-
				ance with 21 CFR
				182.6751).
	Calcium disodium,	To preserve product	Margarine or oleomargarine	75 ppm by weight of the fin-
	EDTA (calcium di- sodium ethylene-	and to protect fla- vor.		ished oleomargarine or margarine.
	diaminetetra-	VOI.		margamo.
	acetate.			
	Calcium propionate	To retard mold	Pizza crust	0.32 percent alone or in
		growth.		combination based on weight of the flour brace
				used.
		do	Fresh pie dough (poultry	0.3 percent of calcium pro-
			only).	pionate or sodium propio- nate alone, or in com-
				bination, based on weight
				of flour used.
	Citric acid	To preserve cured	Cured pork cuts	Not to exceed 30 percent in
		color during stor- age.		water solution used to spray surfaces of cured
		age.		cuts, prior to packaging,
				in accordance with 21
				CFR 184.1033. (The use
				of such solution shall not result in the addition of a
				significant amount of
				moisture to the product
				and shall be applied only
	Citric acid (sodium	To acidify	Margarine and oleo-	once to product). Sufficient for purpose.
	and potassium	10 acidity	margarine.	Camoloni for purpose.
	salts).			
	d- and dl-alpha-to-	To inhibit nitrosa-	Pump-cured bacon	500 ppm; by injection or
	copherol.	mine formation.	I	surface application.

Class of substance	Substance	Purpose	Products	Amount
	Dipotassium phos- phate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohib- ited by the meat inspec- tion regulations and poul- try food products except where otherwise prohib- ited by the poultry prod- ucts inspection regula- tions	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product.  Do.
	Disodium phosphate Glycerine	Humectant	Shelf stable meat snacks	Not to exceed 2 percent of the formulation weight of the product in accordance with 21 CFR 182.1320.
	Hydrochloric acid Lactic acid (sodium and potassium salts).	To acidifydo	Margarine or oleomargarinedo	Sufficient for purpose. Do.
	L-Tartaric acid (so- dium and sodium potassium salts).	do	do	Do.
	Monopotassium phosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product.
	Monosodium phos- phate.	do	do	Do.
	Phosphoric acid Potassium bicarbonate.	To acidify To alkalize	Margarine or oleomargarine Margarine or oleomargarine	Sufficient for purpose. Sufficient for purpose.
	Potassium car- bonate.	do	do	Do.
	Potassium pyrophosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohib- ited by the meat inspec- tion regulations and poul- try food products except where otherwise prohib- ited by the poultry prod- ucts inspection regula- tions.	5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phos- phate in meat food prod- uct (only clear solution may be injected into meat food product). For poultry food products, 0.5 per- cent of total product.
	Potassium sorbate	To retard mold growth.	Dry sausage	10 percent in water solution may be applied to cas- ings after stuffing or cas- ings may be dipped in so- lution prior to stuffing.
	Potassium tripolyphosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohib- ited by the meat inspec- tion regulations and poul- try food products except where otherwise prohib- ited by the poultry prod- ucts inspection regula- tions.	5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product.
	Propyl paraben (propyl p-hydroxy- benzoate).	To retard mold growth.	Dry sausage	3.5 percent in water solution may be applied to cas- ings after stuffing or cas- ings may be dipped in so- lution prior to stuffing.
	Silicon dioxide	Processing aid/dispersant.	Tocopherol containing bacon curing mixes.	At level not to exceed 4.0 percent in the dry mix.

Class of substance	Substance	Purpose	Products	Amount
	Sodium acid pyrophosphate.	To decrease the amount of cooked out juices.	Meat food products except where other prohibited by the meat inspection regu- lations and poultry food products except where otherwise prohibited by the poultry products in- spection regulations	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phos phate in meat food product (only clear solution may be injected into mear food product). For poultry products, 0.5 percent of total product.
	Sodium bicarbonate	To neutralize excess acidity, cleaning vegetables.  To alkalize	Rendered fats, soups, cur- ing pickle (meat and poul- try).  Margarine or oleomargarine	Sufficient for purpose.  Do.
	Sodium carbonate	do	do	Do.
	Sodium citrate buffered with citric acid to a pH of 5.6.	To inhibit the growth of micro-orga- nisms and retain product flavor during storage.	Cured and uncured, proc- essed whole muscle meat and poultry food products, e.g., ham, chicken breasts.	Not to exceed 1.3 percent of the formulation weight of the product in accord- ance with 21 CFR 184.1751.
	Sodium hydroxide	To alkalize	Margarine or oleomargarine Poultry food products containing phosphates.	Sufficient for purpose.  May be used only in combination with phosphate ir a ratio not to exceed one part sodium hydroxide to four parts phosphate.
		do	Meat food products containing phosphates.	May be used only in com- bination with phosphates in a ratio not to exceed one part sodium hydrox- ide to four parts phos- phate; the combination shall not exceed 5 per- cent in pickle at 10 per- cent pump level; 0.5 per- cent in product.
	Sodium metaphosphate, insoluble.	do	Meat food products except where other prohibited by the meat inspection regu- lations, and poultry food products except where otherwise prohibited by the poultry products in- spection regulations.	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into mear food product). For poultry products, 0.5 percent of total product.
	Sodium polyphosphate, glassy.	do	do	Do.
	Sodium proprionate	To retard mold growth.	Pizza crust	0.32 percent alone or in combination based on weight of the flour brace used.
		do	Fresh pie dough (poultry only).	0.3 percent of calcium proprionate or sodium proprionate alone, or in combination, based on weight of flour used.
	l o "	To decrease the	Meat food products except where otherwise prohib-	For meat food products, 5 percent of phosphate in
	Sodium pryophosphate.	amount of cooked out juices.	ited by the meat inspec- tion regulations and poul- try food products except where otherwise prohib- ited by the poultry prod- ucts inspection regula- tions.	pickle at 10 percent pump level; 0.5 percent of phos phate in meat food prod- uct (only clear solution may be injected into mear food product). For poultry products, 0.5 percent of total product.

Class of substance	Substance	Purpose	Products	Amount
	Sorbic acid (sodium, potassium, and calcium salts).	To preserve product and to retard mold growth.	Margarine or oleomargarine	0.1 percent individually, or ir used in combination or with benzoic acid or its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).
	Tricalcium phos- phate.	To preserve product color during dehydration process.	Mechanically deboned chicken to be dehydrated.	Not to exceed 2 percent of the weight of the me- chanically deboned chick- en prior to dehydration, in accordance with 21 CFR 182.1217.
Poultry scald agents (must be removed by subsequent cleaning oper- ations).	Alpha-hydro-omega- hydroxy-poly (oxy- ethylene) poly (oxypropylene) (minimum 15 moles) poly (oxy- ethylene) block copolymer (poloxamer).	To remove feathers	Poultry carcasses	Not to exceed 0.05 percent by weight in scald water.
	Dimethylpolysiloxan-	do	do	Sufficient for purpose.
	e. Dioctyl sodium sulfosuccinate.	do	do	Do.
	Dipotassium phos- phate.	do	do	Do.
	Ethylenediaminetetr- a-acetic acid (so- dium salts).	do	do	Do.
	Lime (calcium oxide, calcium hydrox-ide).	do	do	Do.
	Polyoxyethylene (20) sorbitan monooleate.	do	do	Not to exceed 0.0175 percent in scald water.
	Potassium hydrox- ide.	do	do	Sufficient for purpose.
	Propylene glycol	do	do	Do.
	Sodium acid phos-	do	do	Do.
	phate. Sodium acid	do	do	Do.
	pyrophosphate. Sodium bicarbonate	do	do	Do.
	Sodium carbonate	do	do	Do.
	Sodium dodecylbenzene-sulfonate.	do	do	Do.
	Sodium-2-ethylhexyl sulfate.	do	do	Do.
	Sodium hexametaphosphate.	do	do	Do.
	Sodium hydroxide	do	do	Do.
	Sodium lauryl sul- fate.	do	do	Do.
	Sodium phosphate (mono-, di-, tribasic).	do		Do.
	Sodium pyrophosphate.	do	do	Do.
	Sodium sesquicarbonate.	do	do	Do.
	Sodium sulfate	do	do	Do.
	Sodium tripolyphosphate.	do	do	Do.
	Tetrasodium pyrophosphate.	do	do	Do.

Class of substance	Substance	Purpose	Products	Amount
Proteolytic Enzymes	Aspergillus flavus oryzae group.	To soften tissue	Raw poultry muscle tissue of hen, cock, mature tur- key, mature duck, mature goose, and mature guin- ea, and raw meat cuts.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus oryzae	do	do	Do.
	Bromelin	do	do	Do.
	Ficin	do	dodo	Do.
Refining Agents (must be elimi- nated during proc- ess of manufac- turing).	Acetic acid	To separate fatty acids and glycerol.	Rendered fats (meat only)	Sufficient for purpose.
O,	Bicarbonate of soda	do	do	Do.
	Carbon (purified charcoal).	To aid in refining of animal fats.	do	Do.
	Caustic soda (so- dium hydroxide).	To refine fats	do	Do.
	Diatomaceous earth; Fuller's earth.	do	do	Do.
	Sodium carbonate Tannic acid	do	do	Do.
Rendering agents	Tricalcium phos- phate.	To aid rendering	Animal fats	Do.
	Trisodium phos- phate.	do	do	Do.
Synergists (used in combination with antioxidants).	Citric acid	To increase effec- tiveness of anti- oxidants.	Any meat product permitted to contain antioxidants as provided for in this part.	Not to exceed 0.01 percent based on fat content.
	Malic acid	do	Poultry fats	0.01 percent alone or in combination with anti- oxidants in poultry fats.     0.01 percent based on total
		do	Poultry fats	weight in combination with antioxidants for use in meat products only. 0.01 percent alone or in combination with anti-
				oxidants in poultry fats.
	Monoglyceride cit- rate.	do	Lard, shortening, fresh pork sausage, dried meats and poultry fats.	0.02 percent.
	Monoisopropyl cit- rate.	do	Lard, shortening, oleo- margarine, fresh pork sausage, dried meats.	Do.
		do	Poultry fats	0.01 percent poultry fats.
	Phosphoric acid	do	Lard, shortening, and poultry fats.	0.01 percent.
Tenderizing agents	Aspergillus flavus oryzae group.	To soften tissue	Raw poultry muscle tissue of hen, cock, mature tur- key, mature duck, mature goose, and mature guin- ea, and raw meat cuts.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus oryzae	do		Not more than 3 percent of a 0.8 molar solution.
	Bromelin Calcium chloride		do	Do.
	Calcium chionae	uu	do	<sub> </sub> D0.

#### § 424.22

Class of substance	Substance	Purpose	Products	Amount
	Papain	To soften tissue	Raw poultry muscle tissue of hen, cock, mature tur- key, mature duck, mature goose, and mature guin- ea, and raw meat cuts.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Potassium chloride	do	do	Not more than 3 percent of a 2.0 molar solution.
	Potassium, magne- sium or calcium chloride.	do	do	A solution of approved inor- ganic chlorides injected into or applied to raw meats or poultry cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.

[64 FR 72175, Dec. 23, 1999, as amended at 65 FR 3123, Jan. 20, 2000; 65 FR 34391, May 30, 2000]

#### § 424.22 Certain other permitted uses.

- (a) Under appropriate declaration as required in parts 316 and 317 of this chapter, the following substances may be added to meat:
- (1) General. Common salt, approved sugars (sucrose, cane or beet sugar), maple sugar, dextrose, invert sugar, honey, corn syrup solids (corn syrup, glucose syrup and fructose), wood smoke, vinegar, flavorings, spices, sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, and other food and color additives specified in the chart in paragraph (c) of this section may be added to meat under conditions, if any, specified in this part or in part 317 of this chapter.
- (2) Artificial flavorings. Other harmless artificial flavorings may be added to meat, with the approval of the Administrator in specific cases.
- (3) Coloring matter and dyes. Coloring matter and dyes, other than those specified in a regulation permitting that use in this chapter or in 21 CFR Chapter I, Subchapter A and Subchapter B, may be applied to meat mixed with rendered fat, applied to natural and artificial casings, and applied to such casings enclosing products, if approved by the Administrator

- in specific cases. When any coloring matter or dye is applied to casings, there shall be no penetration of coloring into the product.
- (b) Use of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) in
- (1) Pumped bacon. With respect to bacon injected with curing ingredients and massaged bacon, sodium nitrite shall be used at 120 parts per million (ppm) ingoing or an equivalent amount of potassium nitrite shall be used (148 ppm ingoing); and 550 ppm of sodium or sodium erythorbate (isoascorbate) shall be used. Sodium ascorbate or sodium erythorbate have a molecular weight of approximately 198. Hydrated forms of these substances shall be adjusted to attain the equivalent of 550 ppm of sodium ascorbate or sodium erythorbate.
- (i) The Department shall collect samples of pumped bacon from producing plants and analyze them for the level of nitrosamines by the Thermal Energy Analyzer (TEA). In the event that a TEA analysis indicates that a confirmable level of nitrosamines might be present, additional samples shall be collected and analyzed by gas chromatography. Presumptive positive results

<sup>&</sup>lt;sup>1</sup> [Reserved]
<sup>2</sup> Information as to the specific products for which use of this additive is approved may be obtained upon inquiry addressed to the Labeling and Additives Policy Division, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC

Provided, that its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the desired technical effect as determined in specific cases prior to label approval under §§ 317.4 or 381.32.

4 Special labeling requirements are prescribed in 381.120 for raw poultry chilled in a medium with more than 70 lbs. of salt to 10,000 gals. of water.

must be confirmed by mass spectrometry before being considered positive. If during the interval required for the Department to analyze the confirmatory samples by gas chromatography and mass spectrometry, changes are made in processing procedures which are expected to result in no confirmable levels of nitrosamines in pumped bacon produced by these new procedures, an establishment may submit samples to USDA for analysis upon prior notification and arrangements with USDA. If, however, an establishment furnishes USDA with laboratory results from testing five consecutive lots of pumped bacon produced under the new procedures and the testing is performed by the USDA methodology and procedures, those results will be utilized in making the determination concerning the product produced under the new procedures. Should the results of these tests reveal that confirmable levels of nitrosamines are not indicated in any of the five consecutive lots, the confirmation analysis by USDA shall be terminated and the establishment shall revert to normal monitoring status. In the event the test results continue to indicate nitrosamines, however, USDA shall proceed in its confirmation analysis on the original samples taken for confirmation. If any one of the original samples collected by USDA for confirmation is found to contain confirmable levels of nitrosamines, all pumped bacon in the producing establishment and all future production will be retained. The Department shall sample and analyze such retained pumped bacon for nitrosamines on a lot by lot basis. A production lot shall be that pumped bacon produced by the establishment in any single shift. Samples from any lot of pumped bacon under retention found to contain nitrosamines at a confirmable level shall cause the lot of pumped bacon to be disposed of in a manner to ensure it will not form nitrosamines when cooked. Such disposal may include incorporation of the uncooked pumped bacon as an ingredient of another meat provided it is processed for eating without further preparation in a manner to preclude the formation of nitrosamines. Bacon subsequently produced shall not be retained because of nitrosamines if the

operator of the establishment makes adjustments in the processing of the product and laboratory results obtained by TEA analysis of samples from five consecutive normal sized lots of pumped bacon indicates that the product being produced contains no confirmable levels of nitrosamines. These tests from five consecutive normal sized lots of pumped bacon shall be conducted by the Department. However, if the establishment furnishes the Department with the results of tests conducted under the methodology and procedures used by the Department, such test results will be utilized in making the determination concerning the nitrosamine content of the product. All tests of pumped bacon for nitrosamines under this paragraph (b)(1)(i) shall be made on pumped bacon cooked at 340 degrees F. for 3 minutes on each side. In order to determine that no confirmable levels of nitrosamines are present in a sample tested, the testing must be performed by methodology and procedures that would detect the presence of any nitrosamines at 10 ppb.

- (ii) Notwithstanding the provisions of paragraph (b)(1)(i) of this section, sodium nitrite may be used at:
- (A) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; or
- (B) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 550 ppm sodium ascorbate orsodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as Pediococcus acetolactii or other bacteria demonstrated to be equally effective in preventing the production of botulinum toxin at a level sufficient for the purpose of preventing the production of botulinum toxin.
- (C) The Department shall collect samples of bacon from establishments producing under paragraph (b)(1)(ii) of this section and analyze them for the level of nitrosamines. Samples shall be randomly selected throughout the production of a lot. The actual sampling

#### § 424.22

plans and methods of analysis that are used will result in approximately the same likelihood as under paragraph (b)(1)(i) of this section of having a presumptive positive result when the true mean level of nitrosamines in a production lot is 10 ppb. In the event of a presumptive positive result, the establishment shall become subject to the provisions of paragraph (b)(1)(i) of this section.

- (2) Immersion cured bacon. Immersion cured bacon may be placed in a brine solution containing salt, nitrite and flavoring material or in a container with salt, nitrite and flavoring material. Sodium nitrite shall not exceed 120 ppm ingoing or an equivalent amount of potassium nitrite (148 ppm ingoing) based on the actual or estimated skin-free green weight of the bacon bellies.
- (3) Bacon made with dry curing materials. With respect to bacon made with dry curing materials, the product shall be cured by applying a premeasured amount of cure mixture to the bacon belly surfaces, completely covering the surfaces. Sodium nitrite shall not exceed 200 ppm ingoing or an equivalent amount of potassium nitrite (246 ppm ingoing) in dry cured bacon based on the actual or estimated skin-free green weight of the bacon belly.
- (c) Irradiation of meat food and poultry products.
- (1) General requirements. Meat food and poultry products may be treated to reduce foodborne pathogens and to extend product shelf-life by the use of sources of ionizing radiation as identified in 21 CFR 179.26(a). Official establishments must irradiate meat food and poultry products in accordance with 21 CFR 179.26(b), the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, and the provisions of this section.
- (2) Dosimetry. Official establishments that irradiate meat food and poultry products must have the following procedures in place:
- $\,$  (i) Laboratory operation procedures for determining the absorbed dose value from the dosimeter.
- (ii) Calibration criteria for verifying the accuracy and consistency of any

means of measurement (e.g., time clocks and weight scales).

- (iii) Calibration and accountability criteria for verifying the traceability and accuracy of dosimeters for the intended purpose, and the verification of calibration at least every 12 months. To confirm traceability, establishments must relate, through documentation, the end point measurement of a dosimeter to recognized standards.
- (iv) Procedures for ensuring that the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and such regions are consistent from one product unit to another of like product.
- (v) Procedures for accounting for the total absorbed dose received by the product unit (e.g., partial applications of the absorbed dose within one production lot).
- (vi) Procedures for verifying routine dosimetry, i.e., assuring each production lot receives the total absorbed dose. Establishments may either position one dosimeter at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit in each production lot or use statistically based validation and dose mapping to determine the number and placement of dosimeters in each production lot.
- (vii) Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.
- (viii) Procedures for verifying the integrity of the radiation source and processing procedure. Aside from expected and verified radiation source activity decay for radionuclide sources, the radiation source or processing procedure must not be altered, modified, replenished, or adjusted without repeating dose mapping of product units to redefine the regions of minimum and maximum absorbed dose.
- (3) Documentation. Official establishments that irradiate meat food or poultry products must have the following documentation on premises, available to FSIS:
- (i) Documentation that the irradiation facility is licensed or possesses gamma radiation sources registered

with the Nuclear Regulatory Commission (NRC) or the appropriate State government acting under authority granted by the NRC.

- (ii) Documentation that the machine radiation source irradiation facility is registered with the appropriate State government, if applicable.
- (iii) Documentation that a worker safety program addressing OSHA regulations (29 CFR chapter XVII) is in place.
- (iv) Citations or other documents that relate to incidences in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities.
- (v) A certification by the operator that the irradiation facility personnel will only operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.
- (vi) A certification by the operator that the key irradiation personnel, who monitor or control daily operations, have been trained in food technology, irradiation processing, and radiation health and safety.
- (vii) Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation that those materials comply with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).
- (4) Labeling. (i) The labels on packages of meat food and poultry products irradiated in their entirety, in conformance with this section and with 21 CFR 179.26(a) and (b), must bear the logo shown at the end of this paragraph (c)(4)(i). Unless the word "Irradiated" is part of the product name, labels also must bear a statement such as "Treated with radiation" or "Treated by irradiation." The logo must be placed in conjunction with the required statement, if the statement is used. The statement is not required to be more prominent than the declaration of ingredients required under §317.2(c)(2). Any label bearing the logo or any wording of explanation with respect to this logo must be approved as required by Section 317.4. of this chapter or subparts M and N of part 381.



- (ii) For meat food or poultry products that have been irradiated in their entirety, but that are not sold in packages, the required logo must be displayed to the purchaser with either the labeling of the bulk container plainly in view or a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. In either case, the information must be prominently and conspicuously displayed to purchasers. Unless the word "Irradiated" is part of the product name, the labeling counter sign, card, or other device also must bear a statement such as "Treated with radiation" or "Treated by irradiation." The logo must be placed in conjunction with the required statement, if the statement is used.
- (iii) The inclusion of an irradiated meat food or poultry product ingredient in any multi-ingredient meat food or poultry product must be reflected in the ingredient statement on the finished product labeling.
- (iv) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the stated requirements elsewhere in this section, provided that such statements are not false or misleading. Statements that there has been a specific reduction in microbial pathogens must be substantiated by processing documentation.

[64 FR 72175, Dec. 23, 1999, as amended at 64 FR 72165, Dec. 23, 1999; 65 FR 34391, May 30, 20001

#### § 424.23 Prohibited uses.

(a) Substances that conceal damage or inferiority or make products appear better or of greater value. No substance may be used in or on any meat if it conceals damage or inferiority or makes the

#### Pt. 430

product appear to be better or of greater value than it is. Therefore:

- (1) Paprika or oleoresin paprika may not be used in or on fresh meat, such as steaks, or comminuted fresh meat, such as chopped and formed steaks or patties; or in any other meat consisting of fresh meat (with or without seasoning).
- (2) Paprika or oleoresin paprika may be used in or on chorizo sausage and other meat in which paprika or oleoresin paprika is permitted as an ingredient in a standard of identity or composition in part 319 of this subchapter.
- (3) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid shall not be used in cooked sausages or any other meat; sulfurous acid and salts of sulfurous acid shall not be used in or on any meat; and niacin or nicotinamide shall not be used in or on fresh meat product; except that potassium sorbate, propylparaben (propyl phydroxybenzoate), calcium propionate, sodium propionate, benzoic acid, and sodium benzoate may be used in or on any product, only as provided in 9 CFR Chapter III.
- (b) Nitrates. Nitrates shall not be used in curing bacon.

## PART 430—REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

Sec.

430.1 Definitions.

430.4 Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products.

AUTHORITY: 7 U.S.C. 450; 7 U.S.C. 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 68 FR 34224, June 6, 2003, unless otherwise noted.

#### § 430.1 Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE

product that has the effect of suppressing or limiting the growth of a microorganism, such as L. monocytogenes, in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Readyto-eat product that comes into direct contact with a food contact surface after the lethality treatment in a postlethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called "prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that